

Key Questions for Adolescent Bariatric Surgery**Draft 3**

Teleconference held on February 7, 2007 by Dr. David Flum. Participants included Leah Hole-Curry and Dr. Tom Inge. This draft was updated by emails and Med Director comments from 2/13; and updated based on further emails and comments on 2-20.

Topic: Bariatric surgery is increasingly being applied to adolescents. The cost of the procedures, their associated morbidity and their impact on development and health conditions are the issue underlying this technology review.

Discussion:

Population/Condition: We started by a discussion the different grouping of adolescents. Most people characterize adolescents as 13-21 but there is a thematic difference to discussions and data regarding 18-21 yr olds and 13-17 year olds. It is recommended that the questions be stratified by these 2 groups. The characterization of the condition has typically been based on BMI 40+ with associated health conditions but may be evolving to include 99% of weight curves.

Intervention/Comparator: In the US the 2 approaches that are mainstream enough to study include the RYGB (performed laparoscopically in most patients) and the LAGB. The non-operative comparator is behavioral modification and/or use of medications with an emphasis on the former. Bariatric surgery should be considered an adjunct to conventional treatment instead of a replacement for conventional treatment and these conventional behavior modification interventions should be considered when assessing costs of the surgery.

Outcomes: Weight loss significant to impact health conditions, quality of life and functional status. There is no standard metric for weight loss that defines success in adolescents but 15%+ sustained over at least 1 yr was considered a working benchmark

Safety – Needs to consider the issue of different surgical techniques and unique operative safety issues. For example, LAGB has few up front risks and can be removed with subsequent procedures with risks of erosion of the esophagus, perforation, bleeding, tube complications

Cost – Also must include cost information on different techniques to compare and include downstream costs of secondary interventions, adjustments of the band and repair of the tube/port system in LAGB. Should cost evaluations also include the costs of non-operative interventions?

Dr Inge and Flum have discussed offline the lack of availability of any programs to improve quality and outcomes (i.e. volume, client selection, waiting periods, centers of experience) for pediatric Bariatric Surgical Procedures.

Additional Comments:
Population/Condition: For the purposes of this technology review the differing benefit/risks for pediatric, adolescents and adults are important. Most people characterize pediatric as less than 13 and adolescents as 13-21 yrs old. However, there may be a clinical difference to discussions and data regarding 18-21 yr olds and 13-17 year olds. It is recommended that the questions be stratified by these 3 groups. In addition, the characterization of the condition has typically been based on BMI 40+ in adults; however, other indicators for surgery for those under 21 years of age are not clear.
Intervention/Comparator: In the US the 2 approaches are main stream (RYGB /LAGB performed laparoscopically). Non-operative treatments (i.e. behavioral modification and/or use of medications) may be less risky/costly alternatives as comparators. **Outcomes:** Weight loss may have a significant to impact co-morbid conditions related to weight. There is no standard metrics for weight loss that defines success in

those under 21 but a sustained loss over 1 yr may be a working benchmark with continued improvement/reductions in co-morbid conditions. Safety – The technology review analysis of risk and benefits may differ by surgical techniques and unique operative safety issues. For example; LAGB vs. RYGB may have fewer up front risks (i.e. risks of erosion of the esophagus, perforation, bleeding, tube complications), RYGB vs. LAGB may have better long term outcomes, and both may have other risks (e.g. developmental delays) over less costly/risky alternatives. Cost – Under the HB2575 cost information on different techniques to compare and include downstream costs of secondary interventions for the weight reduction surgeries. Cost evaluations may include costs of non-operative interventions compared to surgeries.

Revised Draft Questions:

1) What is the evidence that Bariatric surgery (RYGB, LAGB or others) is associated reductions in co-morbid conditions linked to obesity (e.g. diabetes, obstructive sleep apnea, musculoskeletal) compared to non-operative approaches in the following age ranges?

- a. in patients 18-21
- b. in patients 13-17
- c. less than 13

2) What is the evidence that Bariatric surgery (RYGB, LAGB or other) is associated with sustained reduction in weight associated co-morbid reductions compared to non-operative approaches in a-c?

3) What is the evidence to compare the safety (i.e. morbidity/mortality) of Bariatric surgery (RYGB, LAGB and other) to non-operative approaches in a-c?

4) What is the evidence to compare the cost of RYGB and LAGB (including downstream costs for adjustment, re-intervention and behavior modification) and non-operative approaches in a-c?

5) Do the effectiveness, safety and cost of Bariatric surgery vary based on age, sex, race, co-morbid conditions (e.g. Pickwickian syndrome), physiologic/skeletal age, starting BMI index, or other demographic/patient variables (psychosocial and socioeconomic determinants)?

6) Does the evidence support greater efficacy and effectiveness of pediatric Bariatric surgery based on BMI (e.g. ≥ 40 or a BMI ≥ 50 with a co-morbid condition) or other indicator(s) for surgery approaches in a-c?